

Blood-Stream Infection (CDC)

From: S. Padovan [spadovan@alcavishdc.com]
Sent: Thursday, December 03, 2009 6:02 PM
To: Blood-Stream Infection (CDC)
Subject: FW: Public Comment on Guidelines for the Prevention of Intravascular Catheter Related Infections
Attachments: Aslte C.PDF; Chua A.PDF; SCAN3655cruz d.pdf; SCAN3657mishkin g 2.pdf; Funes I.PDF; SCAN3658exseptwc510k.pdf; SCAN3660exseptwcrx1.pdf; SCAN3661alcavis50.pdf; SCAN3662alcavis100.pdf

December 3, 2009

Dear Reviewer,

As a Nephrology Nurse, I am submitting comments below on the CDC's "Draft Guideline for the Prevention of Intravascular Catheter-Related Infections," as requested in the Notice of Availability and Request for Public Comment published in the *Federal Register* on November 3, 2009 (74 FR 56843). Our community is pleased that the CDC's draft Guideline continues to evolve. In reviewing this document, I have identified the following three points that provide significant value to clinicians and, therefore, should be included in the guidelines.

1. **Include a separate section for the care of long-term, indwelling catheters such as hemodialysis catheters.** In the 2002 version of the guideline, there was a separate section titled "*Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients,*" and a subsection VI.titled "*Catheter and catheter-site care.*" Subsection VI has been eliminated from the current draft guideline. The CDC should include the following pertinent, updated information under a new separate section in the guidelines for the care of long-term, indwelling catheters such as hemodialysis catheters, as this information is not clearly presented elsewhere in the guideline:
 - A. When a catheter is used for 3 weeks or longer, the risk of infection from insertion site contamination drops, and the risks from hub contamination increase dramatically. Therefore, a section directed towards attention to proper procedure for hub disinfection in dialysis is warranted. As a note, solutions used for hub disinfection of catheters is regulated by the FDA as a medical device and requires a 510K clearance to be marketed for this purpose.
 - B. Site care of catheters in place longer than 2 weeks can become a significant risk of infection if an incompatible solution is used for the care of the catheter. This last statement is mentioned in the guideline, however, the risks which are greater for the long-term catheter use dialysis population are not adequately expressed. The use of alcohol-containing products on catheters of polyurethane material will, in a relatively short time, affect the physical structure of the catheter. Similarly, the use of povidone iodine on silicone catheters will have a comparable deleterious effect. There are very few chlorhexidines without alcohol. Sodium hypochlorite solutions, which are compatible with polyurethane and silicone hemodialysis catheters, have been used in dialysis for more than a decade for routine catheter care at the exit site, as well as, for disinfecting the hubs with outcomes equal to or exceeding povidone iodine and chlorhexidine / alcohol

combinations.

- C. Routine site care is suggested for indwelling dialysis catheters. This is commonly performed at each dialysis session. This results in a minimum of three site cleansing and dressing changes per week. When this is multiplied by the average 12 weeks of catheter duration, the result is at least 36 applications of the site cleanser. The risk of irritation and sensitization, especially to chlorhexidine and povidone iodine products used for the long term, increases and exit sites commonly become inflamed. This increases patient discomfort and possibly the risk of infection due to the broken skin. Sodium hypochlorite solutions, commonly used in dialysis today, have been shown to be non-irritating, non-sensitizing and non-cytotoxic.

In the 2009 USRDS (Vol 2, pg 191), it is reported that more than 80% of all new dialysis patients start hemodialysis with a catheter. Given that a fistula takes at least 4-6 weeks to mature, catheters for dialysis are used for a minimum of 3 weeks, and many times continue to be used as a primary vascular access. Up to 29% of the ESRD patient population has a catheter as their vascular access. The majority of the studies reviewed for this revised guideline are short-term use studies of catheters placed 7 days or less. However, given that dialysis catheters are in place for an average of 3 months, these studies do not directly pertain to dialysis catheters. It is the long-term implantation that yields different risks for infection and, therefore, justifies the need for its own section.

2. **Line 669 – 673: Antibiotic/antiseptic ointment use:** Presented is a new study (accepted for publication) showing the benefits of using antibiotic/antiseptic ointments in conjunction with a sodium hypochlorite skin cleanser for the routine care of catheter exit sites. The study assessed peritoneal dialysis catheters, but the patient population is the same and the exit site microbial challenges are similar to hemodialysis CVC exit sites. The use of both products will address the concerns of fungal infections and microbial resistance presented on lines 465 – 467 of the guideline. (References 109 and 110 from the original 2002 Guideline are studies of the peritoneal dialysis population, and are deemed appropriate.)
3. **Disinfection of catheter limbs and ports/hubs:** On line 216 – 217 it is stated that “direct contamination of the catheter or catheter hub by contact or with contaminated fluids or devices” is a recognized route for contamination of catheters. However, there is little presented in the guideline for the proper disinfection and access of the hubs/ports. Add to the guidelines, as described above, that hemodialysis catheters are frequently at risk of contamination of the hubs. Also, the use of compatible solutions for disinfecting the hubs is important since this solution is commonly used on the catheter itself. Finally, the solution used for the disinfection of a medical device, such as a catheter, is considered a medical device and is regulated as a medical device requiring a FDA 510K clearance.

In the US, there are more than 70,000 long-term indwelling vascular catheters used three times per week to provide treatment to chronic dialysis patients. As a part of the nephrology community, it is important that the Guidelines address the chronic care of these dialysis catheters. Concerns specific to this population of catheters are 1) catheter compatibility, 2) skin irritation from topical products routinely used at the catheter exit site at each dialysis treatment and 3) proper hub/port disinfection. Sodium hypochlorite products have been widely used in dialysis for both routine care of the catheter exit site, as well as, the proper disinfection of the dialysis hubs/ports. I have attached numerous clinical and laboratory studies, as well as, other pertinent information to support the above statements. I would be pleased to provide more details if needed and I can be contacted at 301-330-7597.

Sincerely,

Michele Padovan, RN

Attachments:

1. Astle, C., Jensen, L. (2005). A Trail of ExSept® for Hemodialysis Central Venous Catheters. *Nephrology Nursing Journal*, Vol. 32, No.4, 517-523
2. Chua, A., Goldstein, S., Bell, D., Brewer, E. (2009). Topical Mupirocin/Sodium Hypochlorite Reduces Peritonitis and Exit-Site Infections in Children. Accepted for Publication *Clinical Journal of the American Society of Nephrology*
3. Cruz, D., Ocampo, A., Bredolan, A., Menara, G., Corradi, de Cal, M., Polanco, N., Kuang, D., Nalesso, F., Crepaldi, C., Ronco, C. Effectiveness of Sodium Hypochlorite in the Prevention of Catheter-Related Infections. *Disinfection by Sodium Hypochlorite: Dialysis Applications. Contrib Nephrol.* Basel, Karger, 2007, vol 154, pp97-102
4. Mishkin, G. Compatibility of Electrolytically Produced Sodium Hypochlorite Solutions on Long-Term Implanted Dialysis Catheters. *Disinfection by Sodium Hypochlorite: Dialysis Applications*
Contrib. Nephrol. Basel, Karger, 2007, vol 152, pp72-83
5. Funes, I., Nash, K., Moran, J. Simple Techniques to Decrease Peritonitis Rates. Abstract presented at the 2009 Daily Dialysis Conference
6. 510K FDA Device Approval-ExSept WC Wound Cleanser
7. 510K FDA Device Approval-ExSept WC Skin and Wound Cleanser
8. 510K FDA Approval-Amukin 50% (Alcavis 50) Disinfectant for Catheters
9. 510K FDA Approval-Amuchina 100% (Alcavis 100) Disinfectant

From: S. Padovan

Sent: Thursday, December 03, 2009 2:53 PM

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Cc: Shelly Padovan

Subject: Public Comment on Guidelines for the Prevention of Intravascular Catheter Related Infections